UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MERCK EPROVA AG and MERCK KGaA

Plaintiffs,

08 Civ. 35 (RMB)

-against-

PROTHERA, INC.,

Defendant.

DEFENDANT'S RESPONSE TO PLAINTIFF'S SURREPLY

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ARGUMENT

A. Merck's False Advertising Claim is Clearly Predicated on Implied, Rather than Literal, Falsity

There can be no dispute that, in its Complaint, Merck repeatedly charged Prothera with having made the allegedly false claim that ProThera's products contain "pure L-5-MTHF." *See* Reply Memorandum of Law in Support of Defendant's Motion for Summary Judgment ("Prothera Reply") at 1-2. There likewise can be no dispute that Merck subsequently backpedaled from those false allegations to its current position – that ProThera's labeling merely "connotes", rather than literally states, that the products in question contain a "pure" or "substantially pure" compound. *See* Merck Surreply at 2-3. Merck's claim is at best a claim of implied falsity and Merck has offered no evidence of actual consumer deception.

Merck's claim that the ProThera labeling is literally false because "L-5-MTHF" indicates an industry-recognized standard of chiral purity is not supported by any evidence. Even if true, Merck ignores the fact that the ProThera labeling of its products refer to the quantity of the active dietary ingredient ("L-5-MTHF") that is actually delivered in its products. ProThera does not refer to its mixture as L-5-MTHF. If it were doing so, the amount of the ingredient listed on the label would be twice the amount (i.e. 800 micrograms of mixture as opposed to the 400 micrograms of L-5-MTHF truthfully stated on the label). Merck has admitted that the consumer receives the stated amount of L-5-MTHF in every capsule that ProThera sold. Thus, the best case for Merck is that the ProThera labels are implicitly false because they do not disclose that the L-5-MTHF is delivered in a racemic mixture.

The very documents Merck cites as proof of its claim of literal falsity prove the opposite. Merck cites to its response to a request for admission that states, "Merck contends that the

manner in which L-5-MTHF is listed in ingredients and in advertising of ProThera's products creates and [*sic*] impression to consumer and healthcare professionals that the L-F-MTHF is the L-diastereoisomer only rather than the diastereoisomeric mixture." Merck Surreply at 3. If something about the "manner in which" information is conveyed "creates an impression" that is purportedly false, then, as a matter of law, the statement is not false on its face, but rather can at best be impliedly false. See Memorandum of Law in Support of Defendant's Motion for Partial Summary Judgment ("ProThera's Moving Br.") at 18 and cases cited therein.

Merck likewise quotes the opinion of its scientific expert Jesse Gregory (who has been Merck's paid consultant since 1999) that "[t]he terms L-5-MTHF and 5-MTHF connote different forms of folate…" Merck Surreply at 5. "Connote" is defined at www.dictionary.com to mean "to signify or suggest (certain meanings, ideas, etc.) in addition to the explicit or primary meaning." In other words, the alleged falsehood is communicated by suggestion and context beyond the "explicit" meaning of the terms. Surely, these repeated references to "impressions," "connotations" and the like, *see also* ProThera Reply at 2, are not accidental. Merck's and its expert's careful choice of words cannot disguise the fact that Merck's claim is at best one for implied, rather than express, false advertising.

Merck's insistence that ProThera "through silence admits" that Merck has established literal falsity is equally baseless. It is Merck that remains conspicuously mute in the face of strong evidence disposing of any claim of literal falsity, such as (1) its own 30(b)(6) witness's statement in internal correspondence that, based on Merck's own "in-house analytical data …[ProThera's product] is claiming to contain 1 mg L-5-MTHF, *which is correct* as it contains 2 mg of the racemic 5-MTHF"; or (2) Merck's Scientific Information Specialist's email soliciting feedback from scientists about the correct nomenclature with the proviso that "We are aware of

the fact that this name [L-5-MTHF] is *not unambiguous.*" *See* Defendant's Rule 56.1 Statement ¶¶29, 45 (emphasis added). Labeling which is either subject to a true (*i.e.*, correct) interpretation or is ambiguous and subject to more than one meaning is, as a matter of law, not literally false.

Merck's latest analogy regarding vanilla and marble party cake is as unpersuasive as its now abandoned "pure oxygen tank" and "bag of marbles" attempts. Merck's analogy coyly tries to import visual and taste differences among sweets into arguments involving featureless dietary supplement capsules. The better analogy would be to consider whether a consumer is interested in receiving the minimum daily amount of vitamin C stated on the bottle as opposed to whether the vitamin C is being delivered in the form of citric acid, rose hips or some other source. ProThera's labels truthfully tell the consumer how much of this active dietary ingredient is in every capsule. Moreover, Merck has offered no evidence to show that the consumer has the understanding that L-5-MTHF refers to a particular mixture or source of the ingredient.

The patent decision cited by Merck in its surreply, *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc.*, 348 F.Supp.2d 713 (N.D. West Va.) is not to the contrary. The case stands for the unremarkable proposition that if a patent claim specifies only the L or S isomer, it does not claim a racemic mixture. The question here, however, is whether ProThera's reference to the quantity of L isomer in the vitamin supplements will mislead customers as the source of this isomer. Merck's failure to proffer such evidence is fatal to its claim of false advertising.

B. Merck Has No Evidence That ProThera Intentionally Sought To Deceive Consumers

Merck has no survey to substantiate what consumers understand the message of the ProThera labels to be, cites no case where a plaintiff prevailed on an implied falsity theory without a survey, and provides only three easily rebutted emails as evidence that a "significant number" of consumers have been deceived. To fill this evidentiary vacuum, Merck now argues

for the first time, on a surreply, that its failure of evidence is excused because ProThera "intentionally sought to deceive the public." Merck Surreply at 7. In order to prevail on this new and unacceptably late argument Merck would have to establish that "defendant's deliberate conduct in this regard is of an egregious nature". *Johnson & Johnson *Merck Pharmaceuticals Co. v. SmithKline Beecham Corp.*, 960 F.2d 294, 298 (2d Cir. 1992).

However, the "egregious" standard is so high, *see Stokely-Van Camp, Inc. v. Coca-Cola Co.*, 646 F. Supp. 2d 510, 527, that the presumption is seldom if ever applied, apparent itself in the fact that Merck has not cited one case where intent to deceive or egregious conduct was found. Indeed, courts have refused to find intent to deceive or egregious conduct even where there was evidence that a defendant was warned that a statement might be potentially misleading. *See, e.g., Rexall Sundown, Inc. v. Perrigo Co.*, 651 F. Supp. 2d 9, 37 (E.D.N.Y. 2009); *Stokely-Van Camp, Inc.*, 646 F. Supp. 2d at 528 (S.D.N.Y. 2009). *See also Johnson & Johnson-Merck Consumer Pharmaceuticals Co. v. Rhone-Poulenc Rorer Pharmaceuticals*, 19 F.3d 125, 132 (3d Cir. 1994). Merck relies solely upon a product announcement by ProThera (Spataro Decl., Ex. 2) that was distributed by ProThera specifically to advise its customers that it was no longer using Merck's trademarked Metafolin. Merck also deliberately omits deposition testimony of Janet Ralston explaining her good faith basis for the description of their new Methylfolate product. *See* Declaration of J. Christopher Jensen ("Jensen Decl."), Exh. B. This evidence does not begin to establish ProThera's intent to deceive much less to satisfy the standard of egregious misrepresentation necessary to create a presumption that consumers were deceived.

C. The *Sciele* Opinion Supports Defendant's View of Preclusion Analysis

Sciele Pharma, Inc. v. Brookstone Pharm., LLC, appended to Merck's Surreply, was rendered in the context of an early motion to dismiss, without the benefit of the full record

available here. The *Sciele* complaint alleged that defendant had marketed its prescription drugs as "generic equivalents" to plaintiff's drugs and had its "knockoff products linked to [plaintiff's drugs] in national pharmaceutical databases. Jensen Decl. Exh. A ¶¶37-40. There are no comparable allegations here.

More importantly, in rejecting FDA preclusion, the *Sciele* court applied precisely the standard applicable here, holding that FDA preclusion hinges on "the extent to which the plaintiff relies on the FDCA as a basis for its claim." See Spataro Decl., Ex. 3 at 10. The *Sciele* complaint predicates no claim on any alleged regulatory violation, merely mentioning the FDA in passing. Jensen Decl. Exh. A, ¶33; Spataro Decl. Ex. 3 at 11. Here, Merck (1) expressly pleads its claim as an FDCA violation (Compl. ¶35: "the FDA ruling establishes that it is improper to label ProThera's product, which contains 5-MTHF as containing pure L-5-MTHF"); (2) proffered an FDA regulatory expert to opine on various FDCA regulations ProThera has allegedly violated; and (3) repeatedly accused ProThera of FDA violations in the testimony of its 30(b)(6) witnesses. *See* ProThera's Moving Br. at 12, 14-16. Unlike the *Sciele* plaintiff, Merck has relied upon violations of the FDCA in its complaint and pursued an FDCA-based litigation posture which has consumed the resources of the parties and their experts for two years.

Additionally, because the issue arose under Fed. R. Civ. P. 12(b)(6), the *Sciele* Court had to assume as true plaintiff's allegation that L-MTHF has a "well-established," defined meaning in the scientific community. Spataro Decl. Ex. 3 at 10-11. Once that allegation was presumed, the Court determined that there was no need to "interpret or apply" FDA regulations. *Id.* at 11. The *Sciele* Court was not presented with evidence, such as is in the record here, by which Merck admits that ProThera's product, according to Merck's own testing, delivers the amount of L-5-MTHF isomer stated on ProThera's label. *See* Sahl Decl. Exh. H at MERCK940.

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